Minutes of TES Weekly Status Meeting (PM-8451)
May 17, 2004

Participants

Philip Morris
Candace Adams
Robin Kinser
Denise Mawyer
Bettie Nelson
Jan Oey
Douglas Oliveri
Hans-Juergen Roethig
Mohamadi Sarkar
Barbara Zedler

MDS
Eileen Burns
Jacki Mowitz
Kim Prchal
Maureen Sautter

Covance
Eric Larson
Jill Schultz

The following items were discussed:

Approval of 05/03/04 Minutes
The following correction should be made to the minutes from 05/03/04:

Nicotine data were rerun due to more than one value being reported for several subjects. Mark Bentley will make the appropriate changes. Data will be reviewed by QA and complete data file will be resent to MDS.

Performance Markers
Free and total NNK and DHBMA are complete and database is locked.

UPC Codes
A new data set from etrials has not yet been sent.
ACTION: M. Larson to request that etrials send new data set to MDS.

Source: https://www.industrydocuments.ucsf.edu/docs/hhpx0001

Topography
All computers have been returned. IT is in the process of cleaning the computers. It is estimated that the computers will be cleaned by 05/21 and the letter stating that the computers have been cleaned will sent to Philip Morris on ~05/21.
ACTION: J. Schultz to send letter.

Questionnaire
Candace Adams would like a copy of the questionnaire data. File may be too large to send via email, but can be saved to a disk and mailed to Candace.
ACTION: E. Larson

Data Discrepancies
Following the meeting, Bettie Nelson provided a summary of the data discrepancies and the action to be taken (included at the end of the minutes.
ACTION: M. Larson and E. Larson, please review and

Eric Larson will correct the date on the questionnaire to be the Visit 2 date. Eric will then resend the survey data to MDS (done). MDS can then run another report for age discrepancy.

Harrogate Sample Analysis Timeline
It is estimated that the nicotine data will be sent by 05/21/04.

TES Timeline
No comment

TES Follow-up Study
Project agreement is being reviewed by Covance.

Next Call
Date: June 7, 2004
Time: 1:00 pm CT/2:00 pm ET
Toll Free No.: 888-384-8977 (domestic)
Passcode: 20651

Source: https://www.industrydocuments.ucsf.edu/docs/hhpx0001

DISCREPANCIES AND OTHER ISSUES
Discussed during Monday's (5/17/04) Teleconferences

1. Discrepancies between the cigarette brand as reported from the UPC codes and the survey – Use UPC code. If UPC code is not available, use the brand information from the survey if the FTC tar delivery can be determined.
2. Discrepancies in age between the survey and the CRF – Use AlphaDos as the definitive source for age. Note that the birthdate from AlphaDos and the Visit 2 date were used to calculate the age. The calculated age was then placed in the survey data file.
3. Discrepancies in gender between the survey and the CRF – Use AlphaDos as the definitive source.
4. Discrepancies between urine volumes from the site and CCLS – Barbara will review the discrepancies for plausibility and provide her findings along with a general rule for determining what constitutes a plausible urine volume. I am also trying to check with Covance to determine how urine volume was captured.
5. Ignore discrepancies in urine volume collection dates. Assume 24-hour collection.
6. Implausible temperature and respiration data – As we don't make use of these variables in the analysis, we will not include these in the demographics tables nor in the analyses. No action need be taken.
7. Implausible FEV_1 and FVC values – Barbara will identify what the lower limit of plausibility is for FEV_1 and FVC.
8. Regression plots will also include a line for "all smokers".
9. Regression scatterplots should be provided for each FTC tar delivery group and non-smokers for each biomarker along with fitted lines.
10. If free akaloid > total akaloid – issue still needs to be resolved

Source: https://www.industrydocuments.ucsf.edu/docs/hhpx0001